36. The stent-graft of claim 35, wherein the stent system, in its expanded state, and the graft material each extend from above the one of the renal apertures to below the one of the renal apertures to form a continuous tubular member.

37. The stent-graft of claim 35, further including a radiopaque marker surrounding the perimeter of a respective renal aperture.

38. The stent-graft of claim 35, wherein each renal aperture is larger than the orifice of the respective renal artery.

Remarks

Applicant thanks the Examiner for allowing claim 23 and indicating that claims 21 and 22 would be allowable if rewritten in independent form. Applicant has rewritten claims 21 and 22 in independent form to place these claims in condition for allowance.

Applicant has amended claims 19-22, cancelled claims 2-5, 11-13, 15-18 and 24 without prejudice and added new claims 25-38. No new matter has been entered. For the reasons below, these claims are believed to be allowable.

I. Claims 1 and 6-10 and 14 are patentable over the cited references.

Claims 1, 6-10 and 14 stand rejected under 35 USC § 102 as being anticipated by *Tiefenbrun* (US Patent No. 5,425,765). Applicant respectfully traverses these rejections and, for the reasons set forth below, submit that claims 1, 6-10 and 14 are patentable.

Claim 1 recites a stent-graft having a graft material defining two renal apertures and a stent system for supporting the graft material. None of these features are taught or suggested by the cited references, taken alone or in combination.

Tiefenbrun discloses a graft 10 which includes a tubular member 12, made of a fabric such as Dacron, and an expandable mesh stent 22 attached to one end of the tubular member 12. The stent 22 is provided with a plurality of fenestrations 24-30 for aligning with blood vessel junctions. The tubular member 12 of *Tiefenbrun* lies below the fenestrations 24-30 and, <u>in contrast</u> with the claimed invention, does <u>not</u> define renal apertures. Moreover, no other reference teaches or suggests modifying the graft of

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Tiefenbrun in the claimed manner. For at least these reasons, claim 1 is patentable over the cited references, taken alone or in combination.

Claims 6-10 and 14 depend from claim 1 and recite additional features which, contrary to the assertions in the Office Action, further distinguish these claims from the cited references. For at least these reasons, claims 6-10 and 14 are patentable over the cited references, taken alone or in combination.

II. Claims 19 and 20 are patentable over the cited references.

Claims 19 and 20 stand rejected under 35 USC § 102 as being anticipated by both *Tiefenbrun* and *Cox*. Applicant respectfully traverses these rejections and, for the reasons set forth below, submit that claims 19 and 20 are patentable.

Claim 19, as amended, recites a process of bridging a defect in a main vessel using three-dimensional imaging. In the claimed process, three-dimensional imaging is used to position a contracted graft having a sidewall aperture(s) within the main vessel and align the graft with branch vessels. The graft is then expanded to press against the main vessel.

None of the cited references teaches or suggests the use of three-dimensional imaging in the placement of a graft with one or more sidewall apertures. Moreover, *Cox* fails to teach a sidewall aperture. For at least these reasons, claim 19 is patentable.

Claim 20 further recites that aligning the graft includes partially expanding the graft and rotating the graft, while partially expanded, about its longitudinal axis to align the one or more sidewall apertures with the one or more branch vessels. These features further distinguish from the cited references. In fact, Tiefenbrun teaches away from the claimed partial expanding and aligning by teaching that its graft is deployed by quickly inflating a balloon to forcible expand the stent 22 against the aorta. See col. 3, lines 30-33.

For at least these reasons, claims 19 and 20 are also patentable over the cited references, taken alone or in combination.



III. New claims 25 and 26 are patentable over the cited references.

Claims 25 and 26 depend from patentable claim 1 and further recite features which distinguish from the cited references. Claim 25 recites that at least one of the renal apertures is elongated in a circumferential direction. *Tiefenbrun* fails to teach such features and, in contrast, teaches that its apertures are elongated in a perpendicular direction, i.e., axially or longitudinally. Claim 26 recites that the stent system includes one or more supporting portions each attached to graft material surrounding the perimeter of a respective one of the one or more apertures. None of these features are found in the cited references, taken alone or in combination. *Tiefenbrun*, for example, fails to even teach graft material defining an aperture. For at least these reasons, claims 25 and 26 are patentable over the cited references, taken alone or in combination.

IV. New claims 27 and 28 are patentable over the cited references.

Claims 27 and 28 depend from claim 1 and recite specific AF temperatures for the shape memory alloy of the stent. The claims address different embodiments which can employ different techniques for partially expanding the stent. Claim 27 address the embodiment where the shape memory alloy has an AF temperature of about 37°C or less.. Claim 28 address the embodiment where the shape memory alloy has an AF temperature greater than 37°C and an MS temperature less than about 37°C. None of the cited references address the specific AF temperature (or MS temperature) of a stent for a graft with sidewall apertures. For at least these reasons, claims 27 and 28 are patentable over the cited references, taken alone or in combination.

V. New claim 29 is patentable over the cited references.

Claim 29 depends from claim 19 and recites an embodiment where a threedimensional imaging is used to position and align a graft within an aorta for bridging an aneurysm. By virtue of these additional features and its dependence on claim 19, claim 29 is patentable over the cited references, taken alone or in combination.



VI. New claims 30-34 are patentable over the cited references.

Claims 30-34 depend from allowable claims 21-23 and recite additional features which further distinguish the claims from the cited references. For these reasons, claims 30-34 are patentable over the cited references, taken alone or in combination.

VII. New claims 35-38 are patentable over the cited references.

Claim 35 recites a stent-graft for bridging an aneurysm in an aorta, which includes a graft material defining at least one renal aperture oriented to align with one of the two renal arteries when the stent-graft is in an expanded state and a stent system for supporting the graft material in a contracted state wherein each renal aperture is contracted and the expanded state wherein each renal aperture is expanded. As noted above with respect to claim 1, none of the cited references teaches or suggests a graft material defining apertures for renal arteries. For at least these reasons, claim 35 is patentable over the cited references, taken alone or in combination.

Claims 36-38 depend from claim 35 and recite additional features which further distinguish these claims from the cited references. Claim 36 recites that the stent system, in its expanded state, and the graft material each extend from above the one of the renal apertures to below the one of the renal apertures to form a continuous tubular member. None of the cited references teaches or suggests these features. *Tiefenbrun*, in contrast, teaches that a stent is attached to an end of tubular material.

Claim 37 recites that the stent-graft includes a radiopaque marker surrounding the perimeter of each aperture. Claim 38 recites that each renal aperture is larger than the orifice of the respective renal artery. None of the cited references teaches or suggests these features.

For at least these reasons, claims 35-38 are patentable over the cited references, taken alone or in combination.

Conclusion

In view of the above, Applicant respectfully requests withdrawal of the rejections and allowance of all pending claims.

Should the Examiner believe that an interview may be helpful in further prosecution of this case, the Examiner is invited to contact Applicant's representative at the number listed below.

Respectfully submitted,

Wilfrido R. Castaneda,

By his attorney,

Dated: 104 9, 1999

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